

Key Note Speaker



Dr. Gerald Cross Gerald.M.Cross@va.gov
ACTING UNDER SECRETARY FOR HEALTH
VETERANS HEALTH ADMNINISTRATION
Dr. Gerald Cross was appointed Acting Under
Secretary for Health for the Veterans Health

Administration (VHA) on May 10, 2009. Prior to this appointment, Dr. Cross served as the Principal Deputy Under Secretary for Health (PDUSH) since July 8, 2007.

VA Research

of Comparative

Effectiveness Research

As Acting Under Secretary for Health, Dr. Cross oversees the health care needs of millions of Veterans enrolled in VHA, the nation's largest integrated health care system. With a medical care appropriation of more than \$47 billion, VHA employs more than 239,000 staff at over 1,400 sites, including hospitals, clinics, nursing homes, domiciliaries, and Readjustment Counseling Centers. In addition, VHA is the Nation's largest provider of graduate medical education and a major contributor to medical research.

During his VA career, Dr. Cross has led numerous initiatives to help Veterans. He has been essential in expanding primary care services, mental health services, tele-health, tele-radiology, Vet Center Services, and educational opportunities for health care students. Due to his efforts, a MoU was signed between the VA and the Department of Defense to accelerate access to VA benefits for separating active duty servicemembers. His other initiatives include the hiring of thousands of additional mental health providers, the development of a model of care to reduce the stigma of mental illnesses, improvements in primary care for women Veterans, enhancements in dental services, and screenings and treatment for traumatic brain injury (TBI). In addition to enhancing quality and standards nationwide, Dr. Cross also oversaw initiatives such as VA's highly successful Suicide Prevention Hotline, improvements in rural healthcare access and the new Veteran-Centered, Veteran-Driven model for VA healthcare.

Dr. Cross joined VHA as the National Director of Primary Care in 2004. In 2005, he was promoted to Deputy Chief Patient Care Services Officer. As the PDUSH, he testified frequently in Congress and was interviewed numerous times by the media, speaking about the VA in many public venues.

Dr. Cross, a native of Norfolk, Va., earned his medical degree from California's Loma Linda University in 1977. In 1978, he entered the U.S. Army and completed his residency in Family Medicine at Eisenhower Army Medical Center in 1982. After his residency, Dr. Cross completed a fellowship in Family Medicine at the University of North Carolina, Chapel Hill in 1985. He is board certified in Family Medicine and maintains clinical privileges at the Washington, D.C., VA Medical Center.

During his Army career, Dr. Cross served in many leadership positions including: Teaching Chief, Department Chair, Chief of the Medical Staff, Consultant to The Army Surgeon General, and faculty member at the Uniformed Services University of the Health Sciences. He commanded four Army medical facilities, ranging from a small overseas clinic to the hospital at Fort Hood, Texas—one of the largest Army posts in the nation. He also served as Deputy Commander for Army Medicine in Europe and the Command Surgeon for U.S. Army Forces Command (FORSCOM). As the FORSCOM Surgeon, he supported the training and deployment of medical forces for Operation Noble Eagle, Operation Enduring Freedom, and Operation Iraqi Freedom.

Dr. Cross is a graduate of the Armed Forces Staff College and the Army War College. His military decorations include the Legion of Merit with four oak leaf clusters, the Air Assault Badge, the "A" Proficiency Designator, and the Order of Military Medical Merit. He is a member of the American Medical Association, the Association of Military Surgeons of the United States, the American Academy of Family Physicians, the American Legion, and the Disabled American Veterans.

Speaker Biographies

David Atkins, MD

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DIRECTOR, QUALITY ENHANCEMENT RESEARCH INITIATIVE (QUERI) PROGRAM

DEPT. OF VETERANS AFFAIRS

Dr. David Atkins is the Director of the Quality Enhancement Research Initiative

(QUERI) program in the Office of Research and Development of the Veterans Administration. In that role, he oversees a network of 9 research centers dedicated to studying and improving the implementation of new practices to improve the quality of care in the VA health system. Before coming to the VA, Dr. Atkins spent 12 years at Agency for Healthcare Research and Quality, providing scientific oversight to their work on evidence-based practice, care management, and comparative effectiveness. He is a board certified internist and clinical epidemiologist. He received his MD from Yale University, completed his residency at Univ. of Pittsburgh Medical Center, and received his MPH from U. Washington where he completed a Primary Medicine Fellowship.



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DIRECTOR OF THE DUKE TRANSLATIONAL MEDICINE INSTITUTE,

AND PROFESSOR OF MEDICINE IN THE DIVISION OF CARDIOLOGY AT THE DUKE UNIVERSITY MEDICAL CENTER

Robert Califf, MD is currently Vice Chancellor for Clinical Research, Director of the Duke Translational Medicine Institute, and Professor of Medicine in the Division of Cardiology at the Duke University Medical Center in Durham, North Carolina. For 10 years he was Director of the Duke Clinical Research Institute (DCRI), the largest academic research organization in the world. He is editor-in-chief of Elsevier's American Heart Journal. He has been an author or co-author of more than 650 peer-reviewed journal articles. Dr. Califf led DCRI for many of the best-known clinical trials in cardiovascular disease. In cooperation with his colleagues from the Duke Databank for Cardiovascular Disease, he has written extensively about the clinical and economic outcomes of chronic heart disease. He is considered an international leader in the fields of health outcomes, quality of care, and medical economics. He is Director of the coordinating center for the Centers for Education and Research on Therapeutics, a public–private partnership among AHRQ, the FDA, academia, the medical-products industry, and consumer groups. Dr. Califf graduated from Duke University (summa cum laude) in 1973 and from Duke University Medical School in 1978. He performed his internship and residency at the University of California, San Francisco, and his fellowship in cardiology at Duke University. He is board certified in internal medicine and cardiology and is a fellow of the American College of Cardiology.

Carolyn M. Clancy, MD

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DIRECTOR OF THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

Carolyn M. Clancy, M.D., was appointed Director of the Agency for Healthcare Research and Quality (AHRQ) on February 5, 2003. Prior to her appointment, Dr. Clancy served as the Agency's Acting Director and previously was Director of AHRQ's Center for Outcomes and Effectiveness Research.

Dr. Clancy, who is a general internist and health services researcher, is a graduate of Boston College and the University of Massachusetts Medical School. Following clinical training in internal medicine, Dr. Clancy was a Henry J. Kaiser Family Foundation Fellow at the University of Pennsylvania. She was also an assistant professor in the Department of Internal Medicine at the Medical College of Virginia before joining AHRQ in 1990. Dr. Clancy holds an academic appointment at George Washington University School of Medicine (Clinical Associate Professor, Department of Medicine) and serves as Senior Associate Editor, Health Services Research. She has served on multiple editorial boards and is currently on the board of the Annals of Family Medicine, Annals of Internal Medicine, American Journal of Medical Quality, and Medical Care Research and Review. She is a member of the Institute of Medicine and was elected a Master of the American College of Physicians in 2004.

Dr. Clancy's research interests include improving health care quality and patient safety, and reducing disparities in care associated with patients' race, ethnicity, gender, income, and education. As Director, she launched the first annual report to the Congress on health care disparities and health care quality.



John Concato, MD, MPH

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DIRECTOR, WEST HAVEN VA CLINICAL EPIDEMIOLOGY RESEARCH CENTER

VETERANS AFFAIRS CONNECTICUT HEALTHCARE SYSTEM

Dr. Concato is the Director of the West Haven VA Clinical Epidemiology Research Center (CERC); he is also a Professor of Medicine at Yale University School of Medicine. Combining clinical training in internal medicine with research training in clinical epidemiology, Dr. Concato has a dual focus on issues in patient care and



methods of patient-oriented research. His clinical projects have included assessing the effectiveness of screening for prostate cancer and evaluating prognosis among men diagnosed with prostate cancer. His methodological work seeks to better understand and improve strategies of study design and statistical analysis. Ongoing projects based at the CERC, and supported by the VA Cooperative Studies Program, include using observational methods to assess neuropsychological and mental health outcomes of Operation Iraqi Freedom, and to evaluate the genetics of functional disability in schizophrenia and bipolar illness.

Seth A. Eisen, MD, MSc

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DIRECTOR, HEALTH SERVICES RESEARCH AND DEVELOPMENT

VETERANS AFFAIRS

Seth Eisen, M.D., M.Sc., an internist and epidemiologist, was appointed Director, Health Services Research and Development Service, Office of Research and Development, Department of Veterans Affairs in December, 2006. In this role, he has developed major initiatives in healthcare informatics, health care genomics, pharmacovigilance, and traumatic brain injury research, and research that focuses on methods of improving provider education to improve patient outcomes.

Dr. Eisen was a staff Physician at the St. Louis Veterans Affairs Medical Center for nearly 30 years, and a Professor of Internal Medicine and Psychiatry at Washington University School of Medicine in St. Louis. He was a developer of the Vietnam Era Twin (VET) Registry, a national cohort of 7400 male-male veteran twin pairs, which has been used to investigate genetic and environmental influences on a wide variety of physical and psychiatric health issues and aging. Dr. Eisen has extensive experience with complex issues relating to research design and quality data collection, and the construction, maintenance, and management of large research cohorts and computer databases. He has over 120 peer reviewed publications.

Grant Huang, PhD

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DEPUTY DIRECTOR COOPERATIVE STUDIES PROGRAM

DEPT. OF VETERANS AFFAIRS

Dr. Huang is the Deputy Director for the Cooperative Studies Program (CSP), a division within the Department of Veterans Affairs' Office of Research & Development that designs, conducts, and funds multi-site clinical trials and large-scale epidemiological studies. Since joining CSP in 2004, his responsibilities include managing a network of 11 clinical research centers with expertise in biostatistics, epidemiology, pharmaceutical management, regulatory affairs, health economics, and genomics. Additionally, he has been involved with designing and/or overseeing 60 multi-site clinical research studies, several of which have been published in top-tier journals including the New England Journal of Medicine and the Journal of the American Medical Association. Dr. Huang has a background in biostatistics/epidemiology and behavioral medicine with a particular interest in musculoskeletal disorders, biomechanical and psychological stress, and work organization. Prior to joining VA, he was a faculty member at the Uniformed Services University of the Health Sciences where he continues to help train military physicians and health care providers. He has also led major public health initiatives with the U.S. Army, U.S. Marine Corps, and Department of Defense and serves on various advisory boards in injury prevention, clinical and health services research.

Joel Kupersmith, MD

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CHIEF RESEARCH AND DEVELOPMENT OFFICER

DEPT. OF VETERANS AFFAIRS

Dr. Kupersmith is a graduate of New York Medical College where he also completed his clinical residency in internal medicine. Subsequently, he completed a cardiology fellowship at Beth Israel Medical Center/Harvard Medical School. After research training in the Department of Pharmacology, Columbia College of Physicians and Surgeons, he joined the faculty of the Mt. Sinai School of Medicine where he rose to the rank of



Professor and was Director of the Clinical Pharmacology section. After this he became Chief of Cardiology and V.V. Cooke Professor of Medicine at the University of Louisville and then Professor and Chairperson, Department of Medicine at the College of Human Medicine at Michigan State University.

Dr. Kupersmith then became Dean, School of Medicine and Graduate School of Biomedical Sciences, Vice President for Clinical Affairs at Texas Tech University as well as CEO of the Faculty Practice. In this position there were many advances in the medical center including a comprehensive strategic plan; a marked stepwise drop in faculty attrition rate; legislative initiatives; growth of the research enterprise; important recruitments; many educational initiatives; construction projects; improved scores of entering students and increased number of minority students. In addition, Dr. Kupersmith had an early role in the process to establish a new medical school in El Paso, Texas. Subsequently, Dr. Kupersmith was a Scholar-in-Residence at both the Institute of Medicine and the Association of American Medical Colleges before assuming duties as Chief Research and Development Officer of the VA. In these roles he completed projects and published papers on a number of health and research policy projects including how to fund, oversee and promote effectiveness research, how Academic Medical Centers should be accountable, quality of care in teaching hospitals, regional IRBs, medical manpower and other issues.

Dr. Kupersmith has more than 150 publications and two books. His earlier research interests were in the area of electrophysiology, the causes and treatment of heart rhythm abnormalities and implantable cardioverter defibrillators. His work included delineation of conduction system characteristics in the human heart, unique effects of antiarrhythmic drugs in ischemic tissue as a basis for their antiarrhythmic actions and classification and electrophysiologic consequences of the sodium/potassium pump. Subsequently, he published in the area of cost effectiveness of heart disease treatments and outcomes following heart attacks. Most recently his work has been on health policy issues.

Michael Lauer, MD, FACC, FAHA

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DIRECTOR OF THE DIVISION OF PREVENTION AND POPULATION SCIENCE

National Heart, Lung, and Blood Institute

Michael Lauer, MD, FACC, FAHA, joined the National Heart, Lung, and Blood Institute (NHLBI) in July 2007 as Director of the Division of Prevention and Population Science; he now serves as the Director of the Division of Cardiovascular Sciences. A board certified cardiologist, he received his MD from Albany Medical College in 1985 and underwent post-graduate training within the Harvard University system at Massachusetts General Hospital, Boston Beth Israel Hospital, the Harvard Graduate School of Education, and the Harvard School of Public Health. After completing specialized research training in Cardiovascular Epidemiology at the Framingham Heart Study, he joined the cardiovascular medicine staff of the Cleveland Clinic in 1993. During 14 years at the Clinic, he established a world-renowned clinical epidemiology research program with primary focus on diagnostic testing and comparative effectiveness. His research led to over 200 publications in major medical journals (including New England Journal of Medicine, JAMA, Lancet, and Annals of Internal Medicine), grant support from the American Heart Association and the NIH, and election to the American Society of Clinical Investigation. Dr. Lauer has served as Contributing Editor for JAMA, co-Director of the Cleveland Clinic Coronary Care Unit, Director of Cardiac Clinical Research, and as first Vice-Chair of the Cleveland Clinic IRB. He achieved distinction in medical education, leading the development of an award-winning clinical research curriculum at the newly founded Cleveland Clinic Lerner Medical College at Case Western Reserve University, where he was Professor of Medicine, Epidemiology, and Biostatistics. In November, 2008, he was awarded the prestigious Ancel Keys lectureship at the annual meeting of the American Heart Association. In his current position at NHLBI, Dr. Lauer is leading a \$1.5 billion per year research division that oversees major programs in cardiovascular biology, translation, clinical research, comparative effectiveness, epidemiology, and prevention.

Timothy O'Leary, MD, PhD

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ACTING DEPUTY CHIEF RESEARCH AND DEVELOPMENT OFFICER

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Dr. O'Leary holds a doctorate in physical chemistry from Stanford University and a medical degree from the University of Michigan. He is certified in Anatomic Pathology by the American Board of Pathology, and in Molecular Genetic Pathology by the American Board of Pathology and the American Board of Medical Genetics. Following his appointment to the Department of Army Senior Executive Service, he



chaired the Department of Cellular Pathology at the Armed Forces Institute of Pathology for more than 15 years prior to coming to the Department of Veterans Affairs. He is also a reserve member of the Public Health Service Commissioned Corps, which recalled him to active duty for four months in 2003.

His own research interests include molecular changes in gastric tumors, ultrasensitive detection of biological toxins, and mechanisms of formaldehyde fixation. He is credited with expanding the capacity of the Armed Forces Pathology Institute to include molecular genetics and tissue magnetic resonance microscopy. Dr. O' Leary has co-authored or authored more than 130 scientific papers since 1973 and written numerous book chapters. He edited the 2002 text Advanced Diagnostic Methods in Pathology: Principles, Practice, and Protocols. Dr. O'Leary will serve as Editor-in-Chief of The Journal of Molecular Diagnostics (JMD) beginning Jan. 1, 2010.

Peter Peduzzi, PhD

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DIRECTOR, COOPERATIVE STUDIES PROGRAM COORDINATING CENTER

VA CONNECTICUT HEALTHCARE SYSTEM

Peter Peduzzi, PhD is a VA Research Career Scientist and the Director of the Cooperative Studies Program Coordinating Center at the VA Connecticut Healthcare System, West Haven, CT. He is also a Professor in the Division of Biostatistics at the Yale School of Public Health. He has more than 30 years' experience in the design, conduct and analysis of clinical trials for the VA Cooperative Studies Program. Dr. Peduzzi is a fellow of the American Statistical Association and the past President of the Society for Clinical Trials. He has served on numerous VA and NIH review committees and editorial boards for several journals including as Associate Editor of Controlled Clinical Trials and the Editorial Consultants Board of the Journal of Clinical Epidemiology.

Sebastian Schneeweiss, MD, ScD

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Associate Professor, Medicine and Epidemiology

HARVARD MEDICAL SCHOOL

Sebastian Schneeweiss is Associate Professor of Medicine and Epidemiology at Harvard Medical School and Vice Chief of the Division of Pharmacoepidemiology and Pharmacoeconomics at the Brigham and Women's Hospital where he is Principal Investigator of the DECIDE Research Center on Comparative Effectiveness Research. His research focuses on the comparative effectiveness and safety of biopharmaceuticals and analytic methods to improve the validity of epidemiologic studies using complex healthcare databases. Dr. Schneeweiss is President of the International Society for Pharmacoepidemiology and is Fellow of the American College of Epidemiology, Clinical Pharmacology, and the International Society for Pharmacoepidemiology. He is voting consultant to the Food and Drug Administration and member of multiple scientific advisory boards.

Harold C. Sox, MD, MACP

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EDITOR EMERITUS, ANNALS OF INTERNAL MEDICINE

CHAIR, IOM COMMITTEE ON INITIAL NATIONAL PRIORITIES FOR CER

Harold Sox graduated from Stanford University (B.S. physics) and Harvard Medical School. After serving as a medical intern and resident at Massachusetts General Hospital, he spent two years doing research in immunology at the National Institutes of Health and three years at Dartmouth Medical School, where he served as chief medical resident and began his studies of medical decision making. He then spent 15 years on the faculty of Stanford University School of Medicine, where



he was the chief of the division of general internal medicine and director of ambulatory care at the Palo Alto VA Medical Center. In 1988 he returned to Dartmouth where he served for thirteen years as Joseph M. Huber Professor of Medicine and chair of the department of medicine. He was the Editor of the Annals of Internal Medicine from 2001 to 2009.

Dr. Sox was the President of the American College of Physicians during 1998-1999. He chaired the U.S. Preventive Services Task Force from 1990 to 1995, the Institute of Medicine Committee to Study HIV Transmission through Blood Products, and the Institute of Medicine Committee on Health Effects Associated with Exposures Experienced in the Gulf War. He chaired the Medicare Coverage Advisory Committee of the Center for Medicare Services from 1999 to 2003 and served on the Report Review Committee of the National Research Council from 2000 to 2005. He recently chaired the Institute of Medicine committee to set national priorities for Comparative Effectiveness Research. He also chairs the National Advisory Committee for the Robert Wood Johnson Foundation Physician Faculty Scholars Program and is a member of the Board of Directors of the Foundation for Informed Medical Decision Making. He was elected to the Institute of Medicine of the National Academies in 1993 and to fellowship in the American Association for the Advancement of Science in 2002. His books include Medical Decision Making, Common Diagnostic Tests: Selection and Interpretation, and HIV and the Blood Supply: an Analysis of Crisis Decisionmaking.

Randall S. Stafford, MD, PhD

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Associate Professor of Medicine and Director of the Program on Prevention Outcomes and Practices in the Stanford Prevention Research Center

Dr. Randall S. Stafford is a graduate of Reed College (BA), Johns Hopkins University (MHS), the University of California at Berkeley (MS and PhD), and the University of California at San Francisco (MD). He completed clinical training in primary care internal medicine at the Massachusetts General Hospital (MGH) in Boston and a research fellowship in HIV/AIDS clinical epidemiology at the Centers for Disease Control and Prevention in Atlanta. He is an Associate Professor of Medicine and Director of the Program on Prevention Outcomes and Practices in the Stanford Prevention Research Center. Dr. Stafford's clinical role at Stanford University includes providing patient care in the Stanford Preventive Cardiology Clinic and the Stanford Internal Medicine Clinic. He has broad clinical expertise as a practicing prevention specialist and primary care internist, substantial epidemiological research expertise, and significant experience evaluating patterns of outpatient practice. He also gained relevant administrative skills as Assistant Director of Primary Care Operations Improvement at Massachusetts General Hospital in Boston. Although he is an international leader in analyzing outpatient quality of care, his recent work has transitioned to a focus on the design and testing of interventions to improve outpatient quality of care.

Dr. Stafford has recently been principal investigator on four major federally funded studies: 1) evaluating the relative influence of scientific and promotional determinants of medication prescribing, 2) developing performance measures for outpatient quality of care, particularly prescribing patterns, 3) Evaluating the use of nurse case managers for cardiovascular disease prevention, and 4) Examining strategies for weight management in low-income communities. His current research focuses on: 1) evaluating patterns of medication use, including off-label drug use in the U.S., the use of aspirin for coronary disease prevention, and international comparisons of hypertension management, 2) clinical trial evaluation of the effectiveness of nurse case managers to improve cardiovascular risk management and weight loss, 3) clinical trial evaluation of a dietary supplement for blood pressure control, 4) development and testing of an online bone health improvement tool for consumers, and 5) evaluating the comparative effectiveness of drugs used for the treatment of massive bleeding.

T. Scott Stroup, MD, MPH

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DIVISION OF MENTAL HEALTH SERVICES AND POLICY RESEARCH

COLUMBIA UNIVERSITY

T. Scott Stroup, MD, MPH is principal investigator of the NIMH-sponsored Schizophrenia Trials Network. He was co-principal investigator of the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) Schizophrenia Trial and now leads two other trials comparing the effectiveness of treatment approaches for schizophrenia. In September 2009 he moved from the University of North Carolina at Chapel Hill to Columbia University and the New York State Psychiatric Institute, where he is in the Division of Mental Health Services and Policy Research. Dr. Stroup was

YEARS

of Comparative
Effectiveness Research

most recently Associate Professor of Psychiatry at the University of North Carolina at Chapel Hill and a faculty research fellow at the Cecil G. Sheps Center for Health Services Research.